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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/775,678	02/10/2004	Kurt von Figura	0403	3614

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EXAMINER	
STEADMAN, DAVID J	

ART UNIT	PAPER NUMBER
1656	

DATE MAILED: 05/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/775,678	FIGURA ET AL.	
	Examiner	Art Unit	
	David J. Steadman	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 February 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,7,9,11,16,19,21,32,33,40,44,51,55,56,58,62,68,69 and 77* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *See Continuation Sheet* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims subject to restriction and/or election requirement are 1,7,9,11,16,19,21,32,33,40,44,51,55,56,58,62,68,69 and 77.

DETAILED ACTION

Status of the Application

[1] The Art Unit location of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1656.

[2] Claims 1, 7, 9, 11, 16, 19, 21, 32-33, 40, 44, 51, 55-56, 58, 62, 68-69, and 77 are pending in the application.

[3] Applicant's preliminary amendments to the claims, filed on 2/10/2004 and 2/28/2005, are acknowledged. The claim listing filed on 2/28/2005 replaces all prior versions and listings of the claims.

[4] Receipt of an information disclosure statement, filed on 2/28/2005, is acknowledged.

Election/Restrictions

[5] Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1, 7, 9, 40, 56, and 58, drawn to an isolated nucleic acid molecule, an expression vector, a host cell, a kit comprising an agent that selectively binds to a nucleic acid, a pharmaceutical agent comprising a nucleic acid of claim 1, including SEQ ID NO:1 or 3, and an array comprising nucleic acids encoding SEQ ID NO:2, classified in class 435, subclass 325.

II. Claims 56 and 58, drawn to a pharmaceutical composition comprising SEQ ID NO:4 and a nucleic acid array encoding SEQ ID NO:5, a

pharmaceutical composition comprising SEQ ID NO:45 and a nucleic acid array encoding SEQ ID NO:46, a pharmaceutical composition comprising SEQ ID NO:47and a nucleic acid array encoding SEQ ID NO:48, a pharmaceutical composition comprising SEQ ID NO:49 and a nucleic acid array encoding SEQ ID NO:50, a pharmaceutical composition comprising SEQ ID NO:51 and a nucleic acid array encoding SEQ ID NO:52, a pharmaceutical composition comprising SEQ ID NO:53 and a nucleic acid array encoding SEQ ID NO:54, a pharmaceutical composition comprising SEQ ID NO:55 and a nucleic acid array encoding SEQ ID NO:56, a pharmaceutical composition comprising SEQ ID NO:57 and a nucleic acid array encoding SEQ ID NO:58, a pharmaceutical composition comprising SEQ ID NO:59 and a nucleic acid array encoding SEQ ID NO:60, a pharmaceutical composition comprising SEQ ID NO:61 and a nucleic acid array encoding SEQ ID NO:62, a pharmaceutical composition comprising SEQ ID NO:63 and a nucleic acid array encoding SEQ ID NO:64, a pharmaceutical composition comprising SEQ ID NO:65 and a nucleic acid array encoding SEQ ID NO:66, a pharmaceutical composition comprising SEQ ID NO:67 and a nucleic acid array encoding SEQ ID NO:68, a pharmaceutical composition comprising SEQ ID NO:69 and a nucleic acid array encoding SEQ ID NO:70, a pharmaceutical composition comprising SEQ ID NO:71 and a nucleic acid array encoding SEQ ID NO:72, a pharmaceutical composition comprising SEQ ID NO:73 and a nucleic acid

array encoding SEQ ID NO:74, a pharmaceutical composition comprising SEQ ID NO:75 and a nucleic acid array encoding SEQ ID NO:76, a pharmaceutical composition comprising SEQ ID NO:77 and a nucleic acid array encoding SEQ ID NO:78,

III. Claim 56, drawn to a pharmaceutical composition comprising SEQ ID NO:80, 81, 82, 83, 84, 85, 86, or 87, classified in class 514, subclass 44.

IV. Claim 58, drawn to a nucleic acid array comprising a nucleic acid molecule encoding Iduraonate 2-Sulfatase, Sulfamidase, N-acetylgalactosamine 6-Sulfatase, N-acetylglucosamine 6-Sulfatase, Arylsulfatase A, Arylsulfatase B, Arylsulfatase C, Arylsulfatase D, Arylsulfatase E, Arylsulfatase F, Arylsulfatase G, HSulf-1, HSulf-2, HSulf-3, HSulf-4, HSulf-5, or HSulf-6, classified in class 702, subclass 20.

V. Claim 11, drawn to an isolated FGE polypeptide, classified in class 435, subclass 196.

VI. Claims 16 and 40, drawn to an isolated binding polypeptide that binds to the polypeptide encoded by the nucleic acid of Group I and a kit comprising an agent that selectively binds to the polypeptide encoded by the nucleic acid of Group I, classified in class 530, subclass 350.

VII. Claim 19, drawn to a family of isolated polypeptides, classified in class 435, subclass 196.

VIII. Claim 68, drawn to a pharmaceutical composition comprising a sulfatase produced by a cell that has been contacted with a nucleic acid comprising

the nucleic acid of claim 1 including SEQ ID NO:1 and 3 or SEQ ID NO:4, 45, 47, 49, 51, 53, 55, 57, 59, 61, 63, 65, 67, 69, 71, 73, 75, 77, 80, 81, 82, 83, 84, 85, 86, or 87, classified in class 514, subclass 2.

IX. Claim 69, drawn to an isolated variant allele of a human FGE gene, classified in class 536, subclass 23.2.

X. Claim 77, drawn to a sulfatase-producing cell, classified in class 435, subclass 325.

XI. Claim 21, drawn to a method for determining the level of FGE expression in a subject, classified in class 435, subclass 7.1.

XII. Claim 32, drawn to a method for identifying an agent useful in modulating FGE activity, classified in class 435, subclass 19.

XIII. Claim 33, drawn to a method of diagnosing Multiple Sulfatase Deficiency, classified in class 435, subclass 6.

XIV. Claim 44, drawn to a method for treating Multiple Sulfatase Deficiency by administering an agent that modulates FGE activity, classified in class 514, subclass 789.

XV. Claims 51 and 55, drawn to a method for increasing FGE activity in a cell or a subject and a method for increasing sulfatase activity in a cell using a nucleic acid of claim 1, including SEQ ID NO:1 or 3, classified in class 514, subclass 44.

XVI. Claim 62, drawn to a method for increasing sulfatase activity in a cell or a subject by contacting a cell with SEQ ID NO:4, 45, 47, 49, 51, 53, 55, 57,

59, 61, 63, 65, 67, 69, 71, 73, 75, 77, 80, 81, 82, 83, 84, 85, 86, or 87, classified in class 514, subclass 44.

[6] If applicant should elect the invention of Group II, restriction to a single pharmaceutical composition and corresponding nucleic acid array is also required under 35 U.S.C. 121. In other words, if applicant elects Group II, applicant is further required under 35 U.S.C. 121 to elect a single pharmaceutical composition and corresponding nucleic acid array for examination on the merits.

[7] If applicant should elect the invention of Group III, restriction to a single pharmaceutical composition is also required under 35 U.S.C. 121. In other words, if applicant elects Group III, applicant is further required under 35 U.S.C. 121 to elect a single pharmaceutical composition for examination on the merits.

[8] If applicant should elect the invention of Group IV, restriction to a single nucleic acid array is also required under 35 U.S.C. 121. In other words, if applicant elects Group IV, applicant is further required under 35 U.S.C. 121 to elect a single nucleic acid array for examination on the merits.

[9] If applicant should elect the invention of Group VIII or XVI, restriction to a single nucleic acid is also required under 35 U.S.C. 121. In other words, if applicant elects Group VIII or XVI, applicant is further required under 35 U.S.C. 121 to elect a single nucleic acid for examination on the merits.

[10] If applicant should elect the invention of Group IX, restriction to a single variation or a specific combination of variations is also required under 35 U.S.C. 121. In other words, if applicant elects Group IX, applicant is further required under 35 U.S.C. 121 to

elect a single variation or a specific combination of variations for examination on the merits.

[11] The inventions are distinct, each from the other because:

[12] The inventions of Groups I, II, III, and IV are related as being nucleic acids. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, each of the nucleic acids of Groups I, II, III, IV is structurally distinct, encodes structurally distinct polypeptides, and no single nucleic acid of Groups I, II, III, and IV would render any of the other nucleic acids of Groups I, II, III, and IV obvious to one of ordinary skill in the art.

[13] The inventions of groups V, VII, VIII, IX, and X and the nucleic acids of groups I-IV are patentably distinct inventions for the following reasons. Polypeptides, which are composed of amino acids, and polynucleotides, which are composed of purine and pyrimidine units, are structurally distinct molecules; any relationship between the inventions of groups V, VII, VIII, IX, and X and the nucleic acids of groups I-IV is dependent upon the information provided by the nucleic acid sequence open reading frame as it corresponds to the primary amino acid sequence of the encoded polypeptide. Furthermore, the information provided by the polynucleotides of groups I-IV can be used to make a materially different polypeptide than that of groups V, VII, VIII, IX, and X. For example, a nucleic acid which hybridizes to SEQ ID NO:1, even under

stringent conditions, encompasses molecules which contain point mutations, splice sites, frameshift mutations or stop codons which would result in use of a different open reading frame, and thus encode a protein that lacks any significant structure in common with SEQ ID NO:2. In addition, while a polypeptide of groups V, VII, VIII, IX, and X can made by methods using some, but not all, of the polynucleotides that fall within the scope of groups I-IV, it can also be recovered from a natural source using biochemical means. For instance, the polypeptide can be isolated using affinity chromatography. Also, the polypeptide can be made using purely synthetic means. For these reasons, the inventions of groups V, VII, VIII, IX, and X and the nucleic acids of groups I-IV are patentably distinct.

Furthermore, searching the inventions of groups V, VII, VIII, IX, and X and the nucleic acids of groups I-IV together would impose a serious search burden. In the instant case, the search of the polypeptides and the polynucleotides are not coextensive. The inventions of Groups V, VII, VIII, IX, and X and the nucleic acids of groups I-IV have a separate status in the art as shown by their different classifications. In cases such as this one where descriptive sequence information is provided, the sequences are searched in appropriate databases. There is search burden also in the non-patent literature. Prior to the concomitant isolation and expression of the sequence of interest there may be journal articles devoted solely to polypeptides which would not have described the polynucleotide. Similarly, there may have been "classical" genetics papers which had no knowledge of the polypeptide but spoke to the gene. Searching, therefore is not coextensive. The scope of polynucleotides as claimed extend beyond

the polynucleotide that encodes the claimed polypeptides as explained above; furthermore, a search of the nucleic acid molecules of claim 1, which encompasses "complements" would require an oligonucleotide search, which is not likely to result in relevant art with respect to the polypeptides of groups V, VII, VIII, IX, and X. As such, it would be burdensome to search the inventions of groups V, VII, VIII, IX, and X and the nucleic acids of groups I-IV together.

[14] The polynucleotide of group I and the binding polypeptide of group VI are patentably distinct for the following reasons. The binding polypeptide of group VI includes, for example, antibodies comprising IgG molecules which comprise 2 heavy and 2 light chains containing constant and variable regions, and including framework regions which act as a scaffold for the 6 complementarity determining regions (CDRs). Polypeptides, such as the antibody of group VI which are composed of amino acids, and polynucleotides, which are composed of nucleic acids, are structurally distinct molecules; any relationship between a polynucleotide and polypeptide is dependent upon the information provided by the nucleic acid sequence open reading frame as it corresponds to the primary amino acid sequence of the encoded polypeptide. Binding partners, which encompasses small molecule organic compounds and other polypeptides, are structurally distinct molecules. In the present claims, a polynucleotide of group I will not encode a binding polypeptide of group VI and the binding polypeptide of group VI cannot be encoded by a polynucleotide of group I. Therefore the binding polypeptide and polynucleotide are patentably distinct. The binding polypeptide and polynucleotide inventions have a separate status in the art as shown by their different

classifications. Furthermore, searching the inventions of group I and VI together would impose a serious search burden since a search of the polynucleotide of group I would not be used to determine the patentability of an antibody of group VI, and vice-versa.

[15] The nucleic acids of Groups II-IV and the binding polypeptide of Group VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, and they have different designs, modes of operation, and effects. (MPEP § 802.01and § 806.06). In the instant case, the nucleic acids of Groups II-IV encode polypeptides that do not bind to the binding polypeptide of Group VI and are thus unrelated because there is no structural relationship between the nucleic acids of Groups II-IV and the binding polypeptide of Group VI.

[16] The polypeptide of groups V, VII, IX, and the polypeptide of the cell of Group X and the binding polypeptide of group VI are patentably distinct for the following reasons: While the claims of the inventions of groups V, VI, VII, IX, and X recite polypeptides, in this instance the polypeptide of groups V, VII, IX, and X is a single chain molecule that functions as an enzyme, whereas the polypeptide of group VI encompasses antibodies including IgG which comprises 2 heavy and light chains containing constant and variable regions, and including framework regions which act as a scaffold for the 6 complementarity determining regions (CDRs) that function to bind an epitope. Thus the polypeptide of groups V, VII, IX, and X and the binding polypeptide of group VI are structurally distinct molecules; any relationship between a polypeptide of groups V, VII, IX, and X and a binding polypeptide of group VI is dependent upon the correlation between the scope of the polypeptides that the antibody or binding partner binds and

the scope of the antibodies or binding partners that would be generated using the polypeptide. In this case, the polypeptide of groups V, VII, IX, and X is a large molecule which contains potentially hundreds of regions to which an antibody or binding partner may bind, whereas the binding polypeptide of group VI is defined in terms of its binding specificity to a small structure within the polypeptide encoded by claim 1. Thus the polypeptide of groups V, VII, IX, and X would result in the production of binding partners outside the scope of group VI. Furthermore, a binding polypeptide of group VI would not specifically bind all of the polypeptides of groups V, VII, IX, and X because the polypeptides of group V, VII, IX, and X encompass mutants and variants. Therefore the polypeptide and binding polypeptide are patentably distinct. Furthermore, searching the inventions of groups V, VI, VII, IX, and X together would impose a serious search burden. The inventions have a separate status in the art as shown by their different classifications. A polypeptide and a binding partner each require different searches. An amino acid sequence search of the full-length protein is necessary for a determination of novelty and unobviousness of the protein. However, such a search is not required to identify the binding polypeptide of group VI. Furthermore, antibodies which bind to an epitope of a polypeptide of groups V, VII, IX, and X may be known even if a polypeptide of groups V, VII, IX, and X is novel. Similarly, an amino acid sequence search for fragments of the polypeptide is required to determine the novelty and nonobvious of the binding polypeptide of group VI, however such a search is not required or sufficient to identify all of the polypeptides of groups V, VII, IX, and X. In addition, the technical literature search for the polypeptide of groups V, VII, IX, and X and the binding

polypeptide of group VI are not coextensive, e.g., antibodies or binding partners may be characterized in the technical literature prior to discovery of or sequence of their binding target.

[17] The polypeptide of Group VIII and the binding polypeptide of Group VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, and they have different designs, modes of operation, and effects. (MPEP § 802.01and § 806.06). In the instant case, the binding partner of Group VI does not bind to the polypeptide of Group VIII and are thus unrelated because there is no structural relationship between the polypeptide of Group VIII and the binding polypeptide of Group VI.

[18] The FGE polypeptide of Group V, the mutant FGE polypeptide of Group IX, and the FGE polypeptide of Group X are related to the family of polypeptides of Group VII as combination and sub-combination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the family of polypeptides of Group VII does not require the polypeptide of Group V or IX or the polypeptide of the cell of Group X. The subcombination of Group V or IX has separate utility such as being used as an antigen for producing an antibody and the cell of Group X can be used for protein expression.

[19] The FGE polypeptide of Group V, the sulfatase polypeptide of Group VIII, and the mutant FGE polypeptide of Group IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, and they have different designs, modes of operation, and effects. (MPEP § 802.01and § 806.06). In the instant case, each of the polypeptides of Groups V, VIII, and IX are structurally distinct and no single polypeptide of Groups V, VIII, and IX would render any of the others obvious to one of ordinary skill in the art.

[20] The polypeptides of Groups V, VII, VIII, and IX are related to the cell of Group X as combination and sub-combination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the cell of Group X is not required to comprise the polypeptide of Group V, VII, VIII, or IX. The subcombination of Group V, VII, VIII, or IX has separate utility such as being used as an antigen for producing an antibody.

[21] The family of FGE polypeptides of Group VII and the sulfatase polypeptide of Group VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, and they have different designs, modes of operation, and effects. (MPEP § 802.01and § 806.06). In the instant case, each of the polypeptides of Groups VII and VIII are structurally distinct and would render the other obvious to one of ordinary skill in the art.

[22] The nucleic acids of Groups I-III and the methods of Groups XI, XIII, XV, and XVI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acid of Groups I-III can be used to produce a polypeptide.

[23] The nucleic acids of Groups I-III and the methods of Groups XII and XIV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, and they have different designs, modes of operation, and effects. (MPEP § 802.01and § 806.06). In the instant case, the nucleic acids of Groups I-III are neither made nor used by the methods of Groups XII and XIV.

[24] The nucleic acid of Group IV and the methods of Groups XI-XVI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, and they have different designs, modes of operation, and effects. (MPEP § 802.01and § 806.06). In the instant case, the nucleic acid of Group IV is neither made nor used by the methods of Groups XI-XVI.

[25] The polypeptides Groups V, VII, and IX and the methods of Groups XII, XIII, XV, and XVI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product

(MPEP § 806.05(h)). In the instant case the polypeptides of Groups V, VII, and IX can be used as antigens in the production of antibodies.

[26] The polypeptides Groups V, VII, and IX and the methods of Groups XI and XIV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, and they have different designs, modes of operation, and effects. (MPEP § 802.01and § 806.06). In the instant case, the polypeptides Groups V, VII, and IX are neither made nor used by the methods of Groups XI and XIV.

[27] The polypeptides Groups VI and VIII and the methods of Groups XI-XVI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, and they have different designs, modes of operation, and effects. (MPEP § 802.01and § 806.06). In the instant case, the polypeptides Groups VI and VIII are neither made nor used by the methods of Groups XI-XVI.

[28] The cell of Group X and the methods of Groups XII, XV, and XVI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the cell of Group X can be used for protein expression.

[29] The polypeptides Groups V, VII, and IX and the methods of Groups XI and XIV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, and they have different designs, modes of operation, and

effects. (MPEP § 802.01and § 806.06). In the instant case, the polypeptides Groups V, VII, and IX are neither made nor used by the methods of Groups XI and XIV.

[30] The methods of Groups XI-XVI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, and they have different designs, modes of operation, and effects. (MPEP § 802.01and § 806.06). In the instant case, the methods of Groups VII-XV comprise different method steps, utilize different products, and yield different results.

[31] MPEP § 803 sets forth two criteria for a proper restriction between patentably distinct inventions: (A) The inventions must be independent or distinct as claimed and (B) There must be a serious burden on the examiner. As shown above, each of the inventions of Groups I-XVI are independent or distinct, thus satisfying the first criterion for a proper restriction. MPEP § 803 additionally states that a serious burden on the examiner may be prima facie shown if the examiner shows by appropriate explanation either separate classification, separate status in the art, or a different field of search. Each of the inventions requires a separate patent and non-patent literature and sequence search and thus, co-examination of the inventions of Groups I-XVI would be a serious burden on the examiner.

[32] It is noted that claims 56, 58, 62, and 68-69 will be examined only to the extent the claims read on the elected subject matter.

[33] Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

[34] Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Rejoinder

[35] The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims

and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder.

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Steadman whose telephone number is 571-272-0942. The examiner can normally be reached on Mon to Fri, 7:30 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David J. Steadman, Ph.D.
Primary Examiner
Art Unit 1656